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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,894	01/30/2004	Kobi Iki	00167-491001/02-31-0464	4190
26166 7590 07/07/2010 FISH & RICHARDSON P.C. SMITH & NEPHEW, INC. 150 Minuteman Road Andover, MA 01810				
EXAMINER				
PEFFLEY, MICHAEL F				
ART UNIT		PAPER NUMBER		
3739				
MAIL DATE		DELIVERY MODE		
07/07/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,894

Applicant(s)

IKI ET AL.

Examiner

Michael Peffley

Art Unit

3739

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-60 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5-7, 10, 13-16, 25-30, 36, 39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 8, 11, 12, 17, 20-24, 31-35, 37, 38, 40, 41 and 43-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/23/2009; 1/20/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 23, 2009 has been entered.

Claims 3, 5-7, 9, 10, 13-16, 25-30, 36, 39 and 42 remain withdrawn as being directed to a non-elected invention. Applicant's amendments to the claims have obviated the Drawing objection as well as the 35 USC 112, first paragraph rejection.

Inventorship

In view of the papers filed July 18, 2005, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of inventors Mark Markel and Ryland B. Edwards, III.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 17, 20-23, 31, 33-35, 37, 38, 40, 41, 43-47, 49, 51, 53, 55, 57, 58 and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Wellman et al (6,652,518).

Wellman et al discloses an electrosurgical instrument comprising a shaft (30) defining a longitudinal axis and a flexible portion (col. 6, lines 34) which is enclosed by a portion of a head (40 – Figure 1A). The head is free to pivot (col. 10, lines 56-62) about an axis transverse to the longitudinal axis. The head includes an electrically conductive surface (43,45) and a substantially planar non-conductive surface (41). The conductive surface(s) are recessed with respect to the bottom surface, and projecting from the sidewall (Figure 1c). In as much as the shaft is flexible/malleable, it is inherently configured to passively bias the conductive surface (i.e. head) towards a tissue surface and is arranged such that the transverse axis is offset from the longitudinal axis (see Figure 1A, for example).

Regarding claim 8, the flexible portion may flex in any direction (since the shaft is malleable), and the pivoting member would inherently be configured to pivot about an axis perpendicular to the flex direction.

Regarding claim 17, the recessed electrodes (43,45 - Figure 1C) are clearly arranged on the non-conductive surface to limit penetration of the conductive surface into tissue contact.

Regarding claims 20 and 21, the conductive surface projects from the non-conductive surface (i.e. sidewall), and is recessed relative to the bottom non-conductive surface.

Regarding claims 22 and 23, the non-conductive surface clearly has a much larger surface area than the conductive area, and the conductive area are electrodes (see Figures 1b and 1c).

Regarding claim 31, Figure 1B shows the head member as a substantial parallelepiped shape.

Regarding claims 33-34, Wellman et al clearly disclose the method of using the device including the step of moving the shaft relative to tissue such that the head may pivot 90°. 10, lines 56-62) such that the conductive surfaces are arranged parallel to tissue (Figure 1C).

Regarding claim 35, the elements have been addressed with respect to claim 1 above. Similarly, the elements of claim 37 have been addressed with respect to claim 1, and the examiner maintains the head may be slid across the tissue surface when suction is not being used. Similarly, the method of claim 38 is disclosed by Wellman et al and the examiner maintains the head would be slid across tissue to the desired location while suction is not being applied.

Regarding claims 40, 41 and 43-45, these limitations have been addressed with regard to claims 1 and 22 above.

The limitations of claims 46 and 47 have been addressed previously with respect to claim 1, and the device inherently provides a flexible power lead (labeled "RF" in Figure 1A) coupled through the shaft and to the electrodes. Claims 51, 53, 55, 57 and 60 are all also directed to the flexible lead shown in Figure 1A. Regarding claim 58, these limitations have been addressed with respect to Claim 1 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 48, 50, 52, 54, 56 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wellman et al ('518) in view of the teaching of Haissaguerre et al (6,068,629).

Wellman et al fails to specifically disclose the use of Nitinol wire or a Nitinol tube as the flexible portion. The examiner maintains that the use of Nitinol as a flexible or malleable material is generally well known in the art. As asserted in the previous Office action, Haissaguerre et al specifically teach of using Nitinol (col. 8, line 65) for making flexible portions of a similar device comprising a flexible member connected to a treatment head containing electrodes.

Regarding claims 48, 50, 52, 54, 56 and 59, the examiner maintains that the specific surface area for the conductive area and the non-conductive area would be a matter of obvious design choice for one of ordinary skill in the art. That is, one of ordinary skill in the art would recognize the appropriate sizes necessary for a given procedure and would obviously create a device having the proper dimensions. There is no criticality or unexpected results disclosed in applicant's specification for the particular dimensions of the device, and this is deemed an obvious design consideration.

To have provided the Wellman et al device with a flexible member made from Nitinol or a Nitinol tube would have been an obvious modification for one of ordinary skill in the art, particularly since Haissaguerre et al disclose the use of this material in an analogous RF device having a flexible elongate member connected to a head having RF electrodes.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 8, 11, 12, 17, 20-24, 31-35, 37, 38, 40, 41 and 43-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/999,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '230 application recite the same basic structure with only slightly modified language and obvious design alternatives.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
July 2, 2010